REMARKS

Claims 30-49 are pending in the Application, with claims 30-33, 37-39, 41-43 and 45-49 being withdrawn. Claims 34 and 35 are sought to be amended without prejudice thereto or disclaimer thereof any subject matter contained within the previously presented versions of these claims. Support for the amended claims can be found, for example, throughout the specification and in the original claims. Applicants have not raised any issue of new matter.

I. Maintained Trademark Objections in Specification

The Examiner has objected to Applicants' specification for allegedly improperly using trademarks. Applicants have amended the specification to provide generic chemical terms for the TRITON X-100® and TRIZOL® brand reagents. Support for these amendments can be found respectively in Exhibits A and B, which identify the generic chemical description for these branded products.

Applicants believe that the remaining trademarks used throughout the specification are identified as such and it is believed that the generic goods to which they correspond are readily apparent upon reading the specification. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw all objections pertaining to Applicants' use of trademarks.

II. Maintained Rejections

A. Rejections Under 35 U.S.C. § 112, 1st Paragraph– Written Description

The rejection of claims 34-36, 40 and 44 under 35 U.S.C. § 112, first paragraph is maintained because the claims allegedly contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. . . . " Office Action, page 3. Applicants thank the Examiner for suggesting to "amend the claims to read on the protein that has *the* sequence of SEQ ID NO:10 or the protein that is encoded by *the* nucleic acid sequence of SEQ ID NO:9 . . ." to overcome the rejection. Office Action, page 4,

lines 1-3. Solely to advance prosecution and not in acquiescence to the rejection, Applicants have adopted the Examiner's suggestion and respectfully request that the Examiner reconsiders and withdraws this rejection.

B. Rejections Under 35 U.S.C. § 112, 1st Paragraph– Enablement (Scope)

The rejection of claims 34-36, 40 and 44 under 35 U.S.C. § 112, first paragraph is maintained because the specification allegedly "does not reasonably provide enablement for the myriads of other polypeptides species claimed. . . ." Office Action, page 5. Applicants thank the Examiner for suggesting to "amend the claims to read on the protein that has *the* sequence of SEQ ID NO:10 or the protein that is encoded by *the* nucleic acid sequence of SEQ ID NO:9 . . ." to overcome the rejection. Office Action, page 6, lines 2-4. Solely to advance prosecution and not in acquiescence to the rejection, Applicants have adopted the Examiner's suggestion and respectfully request that the Examiner reconsiders and withdraws this rejection.

C. Rejections Under 35 U.S.C. § 112, 1st Paragraph– Enablement (Vaccine)

The rejection of claims 36 and 40 under 35 U.S.C. § 112, first paragraph is maintained because the claims allegedly "contain[] subject matter which was not describe in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Office Action, page 8. The Examiner asserts that "the specification is devoid of any teaching that said proteins provide an effective vaccine against any disease." *Id.* at last line on page 8. The Examiner also alleges that "it is not clear that the described proteins are capable of generating an active immune response such as an antibody response that protects the animal against any type of disease." *Id.* at 9. Finally, the Examiner concludes that "[i]n view of the lack of support in the art and specification for an effective vaccine comprising the claimed proteins, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled." *Id.* Applicants respectfully disagree with the rejection.

The specification clearly indicates that the claimed protein generates antibody responses from immunized calves. In particular, Applicants respectfully direct the Examiner's attention to Example 2 starting on page 29 of the specification. This example describes the peptide fraction referred to as "ES-thiol" that contains SEQ ID NO.:10. *See* page 30, lines 26-33; and page 31, lines 6-15. *See also* page 28, lines 26-31. Importantly, calves that were immunized with this ES-thiol peptide fraction generated serum antibodies that strongly recognized (*i.e.*, bound) SEQ ID NO.:10. *See* page 30, line 4-13; and page 31, lines 1-4. Hence, in contrast to the Examiner's assertions, Applicants' specification provides strong evidence that the claimed protein can be used as a vaccine. As the Examiner has not provided any non-speculative factually based reasoning to doubt Applicants' claim that SEQ ID NO.:10 can serve as a vaccine, a *prima facie* case that the claims are not enabled has not been established.

In an effort to advance prosecution, Applicants are providing herewith as Exhibit C a journal article that clearly demonstrates that the SEQ ID NO.:10-containing ES-thiol peptide fraction does indeed serve as a vaccine. *See* first paragraph of Exhibit C. Exhibit C describes ES-thiol as a protective antigen fraction (*i.e.*, a vaccine) that contains SEQ ID NO.:10, identified therein as "Oo-ASP2" in Figure 1c. Two additional publications discussing the ability of SEQ ID NO.:10 to serve as a vaccine are also provided herewith as Exhibits D and E.

Hence, Applicants' specification enabled the use of SEQ ID NO.:10 in a vaccine. Accordingly, Applicants respectfully request that the Examiner reconsiders and withdraws this rejection.

D. Rejections Under 35 U.S.C. § 102(b)

Claims 34-36 and 40 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by US Patent 6,017,757 (herein, "the '757 patent"). Office Action, page 10. In particular, the Examiner asserts the following:

> The claims only require that the protein be 30kd and have *a* sequence depicted in SEQ ID NO:10, or be encoded by a nucleic acid that has *a* sequence depicted in SEQ ID NO:9. The claims do not require the protein to actually have the entire sequence of SEQ ID NO:10, or to be encoded by a nucleic acid with the

> entire sequence of SEQ ID NO:9. Only 2 consecutive amino acids or nucleic acids in common are require to meet the limitations of the claims. Therefore, if the proteins disclosed by Coyne do have the aminopeptidase M consensus sequence, and the protein with the amino acid sequence of SEQ ID NO:10 does not, this does not mean that the proteins of Coyne do not meet the limitations of the claims.

Office Action, page 10. Applicants respectfully traverse the rejection.

As discussed above, Applicants have amended claims 34 and 35 to now respectively require as limitations "*the* sequence as depicted in SEQ ID NO: 10" or "*the* nucleic acid sequence as depicted in SEQ ID NO: 9." Accordingly, the assertion that "[o]nly 2 consecutive amino acids or nucleic acids in common are required to meet the limitations of the claims" is now either incorrect and/or moot.

Furthermore, as explained in Applicants' previous response filed on August 24, 2006, the proteins or sequences discussed in the '757 patent are not the same as those claimed by Applicants. The '757 patent states the following:

> Furthermore, these Con-A binding fractions were shown to possess aminopeptidase-M activity. The significance of these data is that analogous proteins of similar molecular weights harvested from parasite intestinal cells possess both aminopeptidase-M activity and Con-A binding avidity (McMichael-Phillips et al., 1995).

See column 25, lines 17-23. Hence, the 29-33 kD proteins identified in the '757 patent have aminopeptidase-M activity.

As discussed in the response filed on August 24, 2006, Aminopeptidase M is an enzyme classified as EC 3.4.11.2, and is also termed Aminopeptidase N. Moreover, all such aminopeptidases have several consensus sequences, as shown by Figure 3 of Knight, P. J. K. *et al., J. Biol. Chem. 270:* 17765-17770 (1995) (previously provided along with August 26, 2006 filing). Because these consensus sequences cannot be found in SEQ ID NO: 10, it is clear that SEQ ID NO: 10 does not belong to the same class of proteins to which the 29-33 kD proteins discussed in the '757 patent belong. Hence, the '757 patent does not anticipate Applicants' SEQ

ID NO: 10 or claims 34-36 and 40. Accordingly, Applicants respectfully request that the Examiner reconsiders and withdraws the rejection.

Moreover, the '757 patent cannot be used to set forth an obviousness rejection of the claims. The M.P.E.P. states that among other requirements

> [t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one or ordinary skill in the art, to modify the reference or to combine reference teachings. . . . [T]he prior art reference (or references when combined) must [also] teach or suggest all the claim limitations.

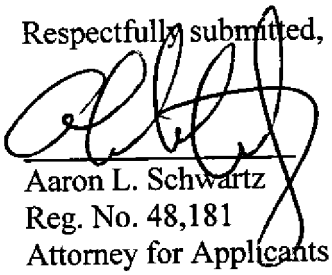
M.P.E.P. 8th ed., §2143 (August 2006 revision). Because there is no suggestion or motivation to modify the '757 patent or to combine it with other references, and because there are no references with which it can be combined to teach or suggest all of the claim limitations, an obviousness rejection based upon the '757 patent cannot be set forth.

III. Conclusion

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 02-2334.

Applicants submit that this application is in condition for allowance, and request that it be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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